DEPARTMENT OF HEALTH AND HUMAN SERVICE

1746d

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
Facsimile: 504-253-4520

September 13, 2001

WARNING LETTER 2001-NOL-56

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John Phillips, Hospital Administrator
Hardy Wilson Memorial Hospital
233 Magnolia Street
Hazlehurst, Mississippi 39083

Dear Mr. Phillips:

A representative of the State of Mississippi, acting on behalf of the U.S. Food and Drug Administration (FDA), inspected your facility on August 29, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal Law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- **1 of 10 random reports reviewed did not contain an assessment category for site.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem has been identified as Level 1, because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to **correct** the violation noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations; and,
- include sample records that demonstrate proper record keeping procedures, if the findings relate to quality control (Phantom QC, Processor QC).

Please submit your response to:

Rebecca A. Asente, Compliance Officer
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U.S. Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the contents of this letter, please feel free to contact Stacy G. Marshall, MQSA Auditor, at (504) 253-4554.

Sincerely,

Patricia K. Schafer

Patricia K. Schafer
Acting District Director
New Orleans District Office

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191

Charles K. Showalter, Senior Director
Government Relations
c/o American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191